K070074

Attachment-6

510(k) SUMMARY
J. Morita USA Inc.'s Lubrina HIM-1

1. Submitter Name and Address with Phone/Fax :

MAY 31 2007

Registration No. 2081055
Initial Distributor:
J. Morita USA, Inc.
9 Mason
Irvine, CA 92618
USA
Telephone: 949-581-9600
Facsimile: 949-581-9688

Registration No. 3002807636
Manufacturer:
J. MORITA MFG. CORP.
680 Higashihama Minami-cho
Fushimi-ku, Kyoto
Japan 612-8533
+81-75-611-2141
+81-75-605-2354

2. **Contact Person**

Keith A. Barritt
Fish & Richardson P.C.
1425 K Street, N.W.
Suite 1100
Washington, DC 20005
Phone: (202) 783-5070
Facsimile: (202) 783-2331

3. **Date summary prepared:**

December 20, 2006

4. **Device Name:**

Common/Usual Name:	Dental handpiece accessory for maintenance, cleaning and lubrication
Trade or Proprietary Name:	LUBRINA
Product Model Name ;	HIM-1
Regulation Number:	21 CFR § 872.4200
Regulation Name :	Dental handpiece and accessories
Regulatory Class :	I
Product Code:	EFB
Classification Panel:	872 Dental.

5. Substantial Equivalency is claimed against the following device:

The LUBRINA HIM-1 is a maintenance system for handpieces, which is used in separate space apart from the patient and dentist. This is commonly used in dentistry, and the device is designed in a similar structure and performance.

· Predicate device

The HIM-1 is substantially equivalent to the Kavo QUATTROcare from KaVo America (K #012308) and the W & H Assistina from A-Dec, Inc. (K #010127). The HIM-1 has similar general intended uses, similar principles of operation, and similar technological characteristics as the previously cleared predicate devices.

Although there are minor differences in the characteristics between the HIM-1 and its predicate device, these differences do not raise new questions of safety or effectiveness.

6. Description of the device:

The LUBRINA HIM-1 is the maintenance system for handpieces, consisting of a main body and several accessories.

The main body is constructed in a box on which the maximum 4 pieces of handpieces are able to be connected by each connection nut, and two spray cans are set inside the box.

7. Indications for use

LUBLINA HIM-1 is intended for internal cleaning, i.e., purging of old lubricant, for the maintenance of rotating dental and surgical instruments.

NOTE: LUBLINA HIM-1 should be used only with pre-cleaned dental handpieces and before they are sterilized.

CAUTION: FEDERAL(US) law restricts the use of this device to licensed professionals.

8. Safety and effectiveness of the device

This device is safe and effective as the other predicate device cited above.
This is better expressed in the tabulated comparison (Section 9 at next page).

9. Substantial Equivalent comparison table

FDA file reference number 510k number K0012308 and K0010127.

TECHNOLOGICAL CHARACTERISTICS	Comparison result
Indication for use	Identical
Target population	Identical
Design	Similar
Materials	Identical
Performance	Similar
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Similar
Human factors	Similar
Energy used and/or delivered	Similar
Compatibility with environment and other devices	Similar
Where used	Identical
Standards met	Similar
Electrical safety	Similar
Thermal safety	Similar

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

J. Morita USA, Incorporated
C/O Mr. Keith A. Barritt
Attorney
Fish & Richardson P.C.
1425 K Street, N.W., Suite 1100
Washington, District of Columbia 20005

MAY 31 2007

Re: K070074
Trade/Device Name: LUBRINA HIM-1
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: May 21, 2007
Received: May 22, 2007

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070074

Indications for Use

510(k) Number (if known): Unknown

Device Name: LUBRINA HIM-1

Indications For Use:

LUBRINA HIM-1 is intended for internal cleaning, i.e., purging of old lubricant, for the maintenance of rotating dental and surgical instruments.

NOTE: LUBRINA HIM-1 should be used only with pre-cleaned dental handpieces and before they are sterilized.

CAUTION: FEDERAL (US) law restricts the use of this device to licensed professionals.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kevin Mulay for KSR

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K070074